

AN ORDINANCE

99419

AUTHORIZING THE EXECUTION OF A VACCINE CLINICAL TRIAL AGREEMENT WITH AVENTIS PASTEUR, INC. WHICH WILL PROVIDE UP TO \$63,800.00 FOR THE PERIOD MAY 1, 2004 THROUGH DECEMBER 31, 2005 FOR THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT TO PARTICIPATE IN A CLINICAL TRIAL STUDY OF DAPTACEL®, WHICH IS A VACCINE THAT PREVENTS THREE CHILDHOOD DISEASES; ESTABLISHING A FUND; ADOPTING THE PROJECT BUDGET; APPROVING THE PERSONNEL COMPLEMENT; AND APPROVING PAYMENTS FOR CONTRACTUAL SERVICES.

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WHEREAS, the San Antonio Metropolitan Health District (SAMHD) operates a program that provides immunizations to children for the prevention of diseases such as measles, rubella, mumps, diphtheria, tetanus, polio, haemophilus influenza b, pertussis, hepatitis A and B, and varicella; and

WHEREAS, Aventis Pasteur Inc., a manufacturer of various pharmaceutical products, has developed DAPTACEL®, which is a vaccine used to immunize children against pertussis, diphtheria, and tetanus; and

WHEREAS, Aventis Pasteur Inc., has offered an agreement to the SAMHD to participate in a clinical trial study of this vaccine during the period May 1, 2004 through December 31, 2005; and

WHEREAS, the City wishes to participate in this effort in order to promote the increased use of this FDA approved vaccine, which is known to prevent these childhood diseases; and

WHEREAS, the SAMHD will receive up to \$63,800.00 for participating in this study; and

WHEREAS, the SAMHD desires to reimburse the families of children enrolled in the study for expenses that may be incurred through their participation in this project; and

WHEREAS, it is now necessary to authorize the execution of this agreement with Aventis Pasteur Inc., establish a fund, adopt the project budget, approve the personnel complement and approve the payment of stipends to each participating parent/guardian in the study; **NOW THEREFORE:**

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:

SECTION 1. The City Manager, or her designee, is hereby authorized to execute a vaccine clinical trial agreement with Aventis Pasteur Inc. for the San Antonio Metropolitan Health District to participate in a clinical trial study of the Daptacel® vaccine for the period May 1, 2004 through December 31, 2005. A copy of this agreement, in substantially correct form, is set out as Attachment II and incorporated herein for all purposes.

SECTION 2. Fund 26-012269 entitled "Daptacel Vaccine Study P3T10" is designated for use in accounting for this project.

SECTION 3. The sum of \$63,800.00 is hereby appropriated in the above-designated fund for the Daptacel Vaccine Study P3T10, and the budget attached hereto and incorporated herein as Attachment I is approved and adopted for entry on the City books.

SECTION 4. Payments in an aggregate amount not to exceed \$4,358.00 are authorized to be paid out to the study's Institutional Review Board (IRB), Cheasapeake Research Review, as required of all research studies to ensure that ethical practices are maintained. Payment will be made from Fund 26-012269, Activity Code 36-07-94, Index No. 648980.

SECTION 5. Payments in an aggregate amount not to exceed \$2,900.00 are authorized to be paid out as stipends to each participating parent/guardian in the clinical study in an amount not to exceed \$50.00 per parent/guardian. Payment will be made from Fund 26-012269, Activity Code 36-07-94, Index No. 649798.

SECTION 6. The two (2) personnel positions set out in Attachment I are hereby authorized for the Daptacel Vaccine Study P3T10.

SECTION 7. The Director of Finance, may, subject to concurrence by the City Manager or the City Manager's designee, correct allocation to specific index codes and fund numbers as necessary to carry out the purpose of this ordinance.

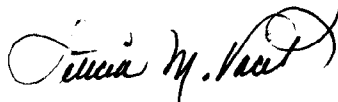
SECTION 8. Should the agreement offered be in an amount other than that budgeted for, or should the agreement contain terms and conditions different than those currently existing, acceptance of the agreement, budget and corresponding personnel complement will be subject to subsequent City Council ordinance.

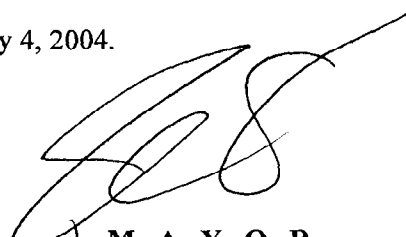
SECTION 9. If an agreement, as first reviewed and approved by the City Attorney, is not signed by both parties within sixty (60) days from the effective date of this ordinance, it becomes null and void, and any further signed documents must be considered by the City Council.

SECTION 10. This ordinance shall be effective on and after July 4, 2004.

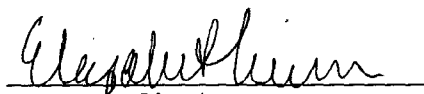
PASSED AND APPROVED this 24th day of June, 2004.

ATTEST:


City Clerk


MAYOR
EDWARD D. GARZA

APPROVED AS TO FORM:


City Attorney